



AP35301 - 072396.0261
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Robbins et al.
Serial No. : 10/650,435 Examiner : Not Yet Assigned
Filed : August 28, 2003 Group Art Unit: 1636
For : POLYPEPTIDES FOR INCREASING MUTANT CFTR CHANNEL
ACTIVITY
Customer No. : 21003

INFORMATION DISCLOSURE STATEMENT

I hereby certify that this paper is being deposited with the
United States Postal Service as first class mail in an envelope
addressed to: Commissioner for Patents, P.O. Box 1450,
Alexandria, VA 22313-1450.

March 18, 2004
Date of Deposit

Carmella L. Stephens
Attorney Name

Carmella L. Stephens
Signature

41,328
Patent Reg. No.

March 18, 2004
Date of Signature

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, applicants respectfully request that the documents
listed below in reverse chronological order and on the accompanying PTO 1449 be considered

by the Examiner and made of record in the above-referenced application. Copies of the documents listed are enclosed.

1. U.S. Patent Application Publication No. 2003/0219826 by Robbins et al., published November 27, 2003.
2. U.S. Patent Application Publication No. 2003/0104622 by Robbins et al., published June 5, 2003.
1. Egan et al., 2002, "Calcium-pump inhibitors induce functional surface expression of $\Delta F508$ -CFTR protein in cystic fibrosis epithelial cells", *Nature Medicine* 8: 485-492.
4. Shwarze et al., 1999, "In Vivo Protein Transduction: Delivery of a Biologically Active Protein into the Mouse", *Science* 285:1569-72.
5. Vocero-Akbani et al., 1999, "Killing HIV-infected cells by transduction with an HIV protease-activated caspase-3 protein", *Nat. Med.* 5:29-33.
6. Sheppard, DN et al., 1999, "Structure and Function of the CFTR Chloride Channel", *Physiol. Rev* 79:S23-45.
7. Elliot et al., 1999, "Intercellular trafficking of VP22-GFP fusion proteins", *Gene Therapy* 6:149-51.
8. Nagahara et al., 1998, "Transduction of full-length TAT fusion proteins into mammalian cells: TAT-p27^{Kip1} induces cell migration", *Nat. Med.* 4:1449-52.
9. Derossi et al., 1998, "Trojan peptides: the penetratin system for intracellular delivery", *Trends in Cell Biology* 8:84-87.
10. Villaverde et al., 1998, "A cell adhesion peptide from foot-and-mouth disease virus can direct cell targeted delivery of a functional enzyme", *Biotechnology and Bioengineering*

59:294-301.

11. Vives et al., 1997, "A Truncated HIV-1 Tat Protein Basic Domain Rapidly Translocates through the Plasma Membrane and Accumulates in the Cell Nucleus", *J. Biol. Chem.* 272:16010-17.
12. Elliot & O'Hare, 1997, "Intercellular Trafficking and Protein Delivery by a Herpesvirus Structural Protein", *Cell* 188:223-233.
13. Moy et al., 1996, "Tat-Mediated Protein Delivery Can Facilitate MHC Class I Presentation of Antigens", *Mol. Biotechnol.* 6:105-13.
14. Howard et al., 1995, "Epitope tagging permits cell surface detection of functional CFTR", *Am J. Physiol.* 269:C1565-76.
15. Fawell et al., 1994, "Tat-mediated delivery of heterologous proteins into cells", *Proc. Natl. Acad. Sci. USA* 91:664-668.
16. Hollenberg et al., 1994, "Multiple promoter elements in the human chorionic gonadotropin β subunit genes distinguish their expression from the luteinizing hormone β gene", *Mol. Cell. Endocrinology* 106:111-119.
17. Goldspiel et al., 1993, "Human gene therapy", *Clinical Pharmacy* 12:488-505.
18. Tolstoshev, 1993, "Gene therapy, concepts, current trials and future directions", *Ann. Rev. Pharmacol. Toxicol.* 33:573-596.
19. Mulligan, 1993, "The Basic Science of Gene Therapy", *Science* 260:926-932.
20. Morgan and Anderson, 1993, "Human Gene Therapy", *Annu. Rev. Biochem.* 62:191-217.
21. 1993, TIBTECH 11(5):155-215.
22. Miller et al., 1993, "Use of Retroviral Vectors for Gene Transfer and Expression", *Meth.*

Enzymol. 217:581-599.

23. Kozarsky and Wilson, 1993, "Gene therapy: advenovirus vectors", *Current Opinion in Genetics and Development* 3:499-503.
24. Wu and Wu, 1991, "Delivery systems for gene therapy", *Biotherapy* 3:87-95.
25. U.S. Patent No. 4,980,286 by Morgan et al., issued December 25, 1990.
26. Green & Lowenstein, 1988, "Autonomous Functional Domains of Chemically Synthesized Human Immunodeficiency Virus Tat Trans-Activator Protein", *Cell*, 55:1179-1188.
27. Frankel & Pabo, 1988, "Cellular Uptake of the Tat Protein from Human Immunodeficiency Virus", *Cell* 55:1189-1193.
28. Wu and Wu, 1987, "Receptor-mediated *in Vitro* Gene Transformation by a Soluble DNA Carrier System", *J. Biol. Chem.* 262:4429-4432.
29. Brinster et al., 1982, "Regulation of metallothionein-thymidine kinase fusion plasmids injected into mouse eggs", *Nature* 296:39-42.
30. Benoist, C. and Chambon, P. 1981, "In vivo sequence requirements of the SV40 early promoter region", *Nature* 290:304-310.
31. Wagner et al., 1981, "Nucleotide sequence of the thymidine kinase gene of herpes simplex virus type1", *Proc. Natl. Acad. Sci. U.S.A.* 78:1441-1445.
32. Yamamoto et al., 1980, "Identification of a Functional Promoter in the Long Terminal Repeat of Rous Sarcoma Virus", *Cell* 22:787-797.

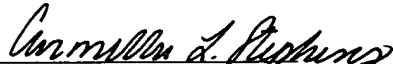
Identification of the listed documents is not to be construed as an admission of the applicants or attorneys for applicants that such citations are available as "prior art" against the subject application. If the Examiner applies the documents as prior art against any claim in the

application and applicants determine that the cited documents do not constitute “prior art” under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

There should be no fee required for this submission. However, if any fee is required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this paper is enclosed.

Respectfully submitted,
BAKER BOTTS L.L.P.


Carmella L. Stephens
PTO Reg. No. 41,328

30 Rockefeller Plaza
44th Floor
New York, NY 10012-4498

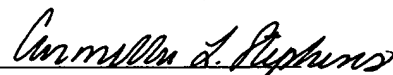
Attorneys for Applicants
(212) 408 2500

application and applicants determine that the cited documents do not constitute “prior art” under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

There should be no fee required for this submission. However, if any fee is required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this paper is enclosed.

Respectfully submitted,
BAKER BOTTS L.L.P.


Carmella L. Stephens
PTO Reg. No. 41,328

30 Rockefeller Plaza
44th Floor
New York, NY 10012-4498

Attorneys for Applicants
(212) 408 2500

Form PTO-1449 U.S. Department of Commerce
(REV. 2-82) Patent and Trademark Office

MAR 23 2004

Atty. Docket No.
AP35301 - 072396.0261

Serial No.
10/650,435

**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**
(Use several sheets if necessary)

Applicants
Robbins et al.

Filing Date
August 28, 2003

Group
1636

U.S. PATENT DOCUMENTS

*Exam. Init.	Document No.	Date	Name	Class	Subclass	Filing Date if Appropriate
	4 9 8 0 2 8 6	12/25/90	Morgan et al.	435	371	

FOREIGN PATENT DOCUMENT

Document No.	Class	SubClass	Translator Yes No

OTHER DOCUMENTS (including Author, Title Date, Pertinent Pages, Etc.)

	U.S. Patent Application Publication No. 2003/0219826 by Robbins et al., published November 27, 2003.
	U.S. Patent Application Publication No. 2003/0104622 by Robbins et al., published June 5, 2003.
	Egan et al., 2002, "Calcium-pump inhibitors induce functional surface expression of $\Delta F508$ -CFTR protein in cystic fibrosis epithelial cells", <i>Nature Medicine</i> 8: 485-492.
	Shwarze et al., 1999, "In Vivo Protein Transduction: Delivery of a Biologically Active Protein into the Mouse", <i>Science</i> 285:1569-72.
	Vocero-Akbani et al., 1999, "Killing HIV-infected cells by transduction with an HIV protease-activated caspase-3 protein", <i>Nat. Med.</i> 5:29-33.
	Sheppard, DN et al., 1999, "Structure and Function of the CFTR Chloride Channel", <i>Physiol. Rev</i> 79:S23-45.
	Elliot et al., 1999, "Intercellular trafficking of VP22-GFP fusion proteins", <i>Gene Therapy</i> 6:149-51.
	Nagahara et al., 1998, "Transduction of full-length TAT fusion proteins into mammalian cells: TAT-p27 ^{Kip1} induces cell migration", <i>Nat. Med.</i> 4:1449-52.
	Derossi et al., 1998, "Trojan peptides: the penetratin system for intracellular delivery", <i>Trends in Cell Biology</i> 8:84-87.

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce
(REV. 2-82) Patent and Trademark Office

Atty. Docket No.
AP35301 – 072396.0261

Serial No.
10/650,435

**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

(Use several sheets if necessary)

Applicants
Robbins et al.

Filing Date
August 28, 2003

Group
1636

		Villaverde et al., 1998, "A cell adhesion peptide from foot-and-mouth disease virus can direct cell targeted delivery of a functional enzyme", <i>Biotechnology and Bioengineering</i> 59:294-301.
		Vives et al., "A Truncated HIV-1 Tat Protein Basic Domain Rapidly Translocates through the Plasma Membrane and Accumulates in the Cell Nucleus", <i>J. Biol. Chem.</i> 272:16010-17 (1997).
		Elliot & O'Hare, 1997, "Intercellular Trafficking and protein Delivery by a Herpesvirus Structural Protein", <i>Cell</i> 188:223-233.
		Moy et al., 1996, "Tat-Mediated Protein Delivery Can Facilitate MHC Class I Presentation of Antigens", <i>Mol. Biotechnol.</i> 6:105-13.
		Howard et al., 1995, "Epitope tagging permits cell surface detection of functional CFTR", <i>Am J. Physiol.</i> 269:C1565-76.
		Fawell et al., 1994, "Tat-mediated delivery of heterologous proteins into cells", <i>Proc. Natl. Acad. Sci. USA</i> 91:664-668.
		Hollenberg et al., 1994, "Multiple promoter elements in the human chorionic gonadotropin β subunit genes distinguish their expression from the luteinizing hormone β gene", <i>Mol. Cell. Endocrinology</i> 106:111-119.
		Goldspiel et al., 1993, "Human gene therapy", <i>Clinical Pharmacy</i> 12:488-505.
		Tolstoshev, 1993, "Gene therapy, concepts, current trials and future directions", <i>Ann. Rev. Pharmacol. Toxicol.</i> 33:573-596.
		Mulligan, 1993, "The Basic Science of Gene Therapy", <i>Science</i> 260:926-932.
		Morgan and Anderson, 1993, "Human Gene Therapy", <i>Annu. Rev. Biochem.</i> 62:191-217.
		1993, <i>TIBTECH</i> 11(5):155-215.
		Miller et al., 1993, "Use of Retroviral Vectors for Gene Transfer and Expression", <i>Meth. Enzymol.</i> 217:581-599.
		Kozarsky and Wilson, 1993, "Gene therapy: advenovirus vectors", <i>Current Opinion in Genetics and Development</i> 3:499-503.

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce
(REV. 2-82) Patent and Trademark Office

Atty. Docket No.
AP35301 - 072396.0261

Serial No.
10/650,435

**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**
(Use several sheets if necessary)

Applicants
Robbins et al.

Filing Date
August 28, 2003

Group
1636

Wu and Wu, 1991, "Delivery systems for gene therapy", *Biotherapy* 3:87-95.

Green & Lowenstein, 1988, "Autonomous Functional Domains of Chemically Synthesized Human Immunodeficiency Virus Tat Trans-Activator Protein", *Cell*, 55:1179-1188.

Frankel & Pabo, 1988, "Cellular Uptake of the Tat Protein from Human Immunodeficiency Virus", *Cell* 55:1189-1193.

Wu and Wu, 1987, "Receptor-mediated *in Vitro* Gene Transformation by a Soluble DNA Carrier System", *J. Biol. Chem.* 262:4429-4432.

Brinster et al., 1982, "Regulation of metallothionein-thymidine kinase fusion plasmids injected into mouse eggs", *Nature* 296:39-42.

Benoist, C. and Chambon, P. 1981, "*In vivo* sequence requirements of the SV40 early promoter region", *Nature* 290:304-310.

Wagner et al., 1981, "Nucleotide sequence of the thymidine kinase gene of herpes simplex virus type1", *Proc. Natl. Acad. Sci. U.S.A.* 78:1441-1445.

Yamamoto et al., 1980, "Identification of a Functional Promoter in the Long Terminal Repeat of Rous Sarcoma Virus", *Cell* 22:787-797.

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.